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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,646	02/23/2004	Joseph P. Errico	F-269	8184
530 7590 02/26/2008 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090				
EXAMINER PELLEGRINO, BRIAN E				
ART UNIT		PAPER NUMBER		
3738				
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02/26/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/784,646

**Applicant(s)**

ERRICO ET AL.

**Examiner**

Brian E. Pellegrino

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date 11/26/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,4,5,9-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser et al. (6478800) in view of Marnay (5314477). Fraser et al. show (Fig. 1) a tool for implanting a disc in an intervertebral space comprising a shaft **20**, two distal extensions **12A**, **14A** and a pin **20A** located between the extensions. It can also be seen there is a "trial" **24** having two halves located between and engaged with the extensions. Fig. 4 shows the outward facing edges have smooth surfaces. Fraser also illustrates the extensions are coupled to a fulcrum **16**. It can be construed that there are flanges at the end of the end of the shaft, see Fig. 7. However, Fraser et al. fail to teach the trial halves are separate such that separation of the extensions move the trial halves. Marnay teaches (Fig. 1) a spinal prosthesis with two halves that can pivot. Marnay also teaches (Fig. 10) that there is an insertion tool for separating or applying force to the halves, col. 6, lines 66-68. It would have been obvious to one of ordinary skill in the art to utilize a trial with two halves as taught by Marnay with the apparatus of Fraser et al. such that the implant can provide the ability to pivot or maintain natural spinal motion. It should also be noted that as the pivoting capability taught by Marnay is incorporated into the apparatus of Fraser

it clearly allows for a varying separation to occur between the upper and lower halves of the implant.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser et al. '800 in view of Marnay '477 as applied to claim 1 above, and further in view of Ripple et al. (4566466). Fraser in view of Marnay is explained supra. However, Fraser as modified by Marnay fail to teach markings for sizing. Ripple et al. teach (Figs. 6,7) markings for sizing a disc to be implanted. It would have been obvious to one of ordinary skill in the art to use markings as taught by Ripple et al. with the apparatus of Fraser in view of Marnay such that the proper implant can be determined for the patient. It is well known in the art to use markings on shafts and would have been obvious to one of ordinary skill in the art to incorporate markings on a shaft of Fraser as modified by Marnay. It would have been an obvious matter of design choice to modify the dimensions of the disc size, since applicant has not disclosed that using 13mm-20mm provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the sizes taught by Ripple or the claimed range of 13-20mm in claim(s) 8 because both apparatus perform the same function of finding the appropriate size for the patient.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser et al. '800 in view of Marnay '477 as applied to claim 1 above, and further in view of Baumgartner (5370697). Fraser as modified by Marnay is explained above. However, Fraser in view of Marnay fail to teach a dome outer

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surface on the implant. Baumgartner shows (Fig. 5) a vertebral contact element **44** having a resting shape of a dome convexly extending from an orthopedic device **2**. It would have been obvious to one of ordinary skill in the art to utilize a dome outer surface on the implant as taught by Baumgartner with the apparatus of Fraser in view of Marnay such that it can be placed within the vertebrae's contour.

### ***Response to Arguments***

Applicant's arguments filed 11/26/07 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant alleges that one would not combine the Marnay teachings with Fraser since the Applicant states Marnay uses the pliers differently. However, comparing uses of the apparatus is a moot point since the claims are directed to product claims and not methods of use. A reference can be said to teach the claimed limitation regardless of how it is used so long as it can perform the claimed function. Clearly, both Fraser and Marnay teach apparatus fully capable of distracting vertebrae. However, it appears that the rejection was misunderstood. The only teaching the Examiner intended to convey from the Marnay reference was and required by the claims is that there was two trial halves that can have varying distances there between. Marnay

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clearly teaches a spinal prosthesis that does pivot and possesses this function. In Fraser's delivery device, the implant is delivered between the extensions and will cause its one end pivot as result of a pivotable implant being inserted through it. A larger separation will result on one side of the implant and a closer separation on the other that is pushed into the vertebral space and once between the vertebrae and the tool is removed the separation will then become the same on both sides as the implant supports the vertebrae.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Brian E Pellegrino/  
Primary Examiner, Art Unit 3738